

PRODUCT INFORMATION

Product SKU	HCVH102
Product Name	HCV High Run Control
Kit Lot Number	64514779
Source Material	Recombinant HCV
Date of Manufacture	2022-10-19
Date of Expiration	2025-09-30
Base Matrix	True EDTA Plasma
Preservative	ProClin® 300
Fill Volume	1.0 mL
Storage Temperature	-20°C or below
Intended Use	CE-IVD
Traceability	4 th HCV International Standard (06/102)
Testing Platform	In-House HCV Assay

This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

TESTING DATA

Lot Number	Product Description	Target Concentration	Testing Results	Quantity
64514779	HCV High Run Control	1,000,000 IU/mL	Pass (Comparison of target value against reference standard)	5 Vials

Bioburden Testing Results	
Acceptance Criteria: Less than 10 CFU/mL	Pass

APPROVAL

Quality Assurance	Date
<i>[Signature]</i>	26 OCT 22